

November 7, 2022



Ocuphire Pharma Enters into a Global License Agreement for Development and Commercialization of Nyxol Eye Drops for Reversal of Mydriasis, Presbyopia and Night Vision Disturbances

Ocuphire to Receive \$35 Million Upfront, Nyxol Development Funding and Additional Potential Milestone Payments plus Tiered Double-Digit Royalties

Strengthened Financial Position Supports Operations and APX3330 Program into 2025

Conference Call Tomorrow November 8, 2022 at 8:30 AM ET

FARMINGTON HILLS, Mich., Nov. 07, 2022 (GLOBE NEWSWIRE) -- Ocuphire Pharma, Inc. (Nasdaq: OCUP) today announced it has concluded an exclusive license agreement with FamyGen Life Sciences, Inc. (Famy) for the development and commercialization of Nyxol across three indications in US, Europe, Japan, India, China and other global markets. In connection with its separately announced transaction with Famy, Viatris Inc. (Nasdaq: VTRS), a leading global healthcare company, has agreed to commercialize Nyxol following each regulatory approval.

"Famy and Ocuphire have been engaging for several months, in a collaborative spirit, to conclude this agreement. This partnership provides a clear pathway to completing development and regulatory activities and executing a successful US and global commercial launch of Nyxol through Viatris," said Mina Sook, MBA, founder and CEO of Ocuphire. "With its strategic commitment to ophthalmics and its global commercial infrastructure, we believe Viatris provides a great opportunity for all of the Nyxol indications to realize their full commercial potential in their respective markets. In addition, the upfront payment and development funding provided by this transaction markedly improve our cash position into 2025, allowing us to expedite the registration trials for presbyopia and night vision disturbances and to execute our late-stage development strategy for the APX3330 retina program."

Under the terms of the license agreement, Ocuphire will receive an upfront cash payment of \$35 million. Famy will fund Nyxol development through FDA approvals, that will be managed by Ocuphire, including clinical, manufacturing, and regulatory activities required for FDA approval of all three Nyxol indications, including Nyxol+Low-Dose Pilocarpine. With the upcoming NDA submission for the reversal of mydriasis indication this quarter, Ocuphire has the potential to receive a \$10 million milestone payment upon FDA approval later in 2023

and thereafter to receive additional regulatory milestones for presbyopia and night vision disturbances indications. In addition to funding Ocuphire's development of Nxyol in the US, Famy will undertake development in the non-US markets.

Upon commercialization, Ocuphire will receive tiered double-digit royalties on worldwide net sales through 2040 and is eligible to receive sales milestone payments upon achievement of certain annual sales thresholds.

Conference Call Details:

Date: November 8, 2022

Time: 8:30 AM ET

Dial-in information: 1-888-886-7786 (US); 1-416-764-8658 (International)

Passcode: 21367120

[Webcast link](#)

A link to the webcast can also be found on the "News and Media" section of Ocuphire's corporate website at <https://www.ocuphire.com/news-media/events>.

About Ocuphire Pharma

Ocuphire is a publicly traded (Nasdaq: OCUP), clinical-stage, ophthalmic biopharmaceutical company focused on developing and commercializing small-molecule therapies for the treatment of refractive and retinal eye disorders.

The Company has a collaboration with FamyGen Life Sciences and Viatris to develop and commercialize Nyxol[®] eye drops (0.75% phentolamine ophthalmic solution), as a once-daily, preservative-free eye drop formulation of phentolamine mesylate, a non-selective alpha-1 and alpha-2 adrenergic antagonist designed to reduce pupil size and is being developed for three indications, including reversal of pharmacologically-induced mydriasis (RM), presbyopia and dim light or night vision disturbances (NVD), pending regulatory approval. Nyxol is currently in Phase 3 for presbyopia and NVD, and ready for NDA submission for RM in Q4 2022.

The Company's product candidate APX3330 is an oral tablet designed to inhibit angiogenesis and inflammation pathways relevant to retinal and choroidal vascular diseases, such as diabetic retinopathy (DR) and diabetic macular edema (DME). APX3330 has been studied in 11 Phase 1 and 2 trials. The Company announced the completion of last patient last visit in late August with top-line results expected in early 2023 ([NCT04692688](#)).

For more information, visit www.ocuphire.com

About FamyGen Life Sciences

FamyGen Life Sciences (Famy) is a drug development focused company, engaged in identifying and in-licensing clinical-stage assets and providing development expertise & strategic funding to advance them towards regulatory approvals. Famy has built a strong ophthalmic portfolio, making significant investments dedicated to bringing innovative ophthalmic therapies to the market.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements concerning Ocuphire’s potential receipt of payments, including regulatory and sales milestone payments, Ocuphire’s potential receipt of royalty payments, Ocuphire’s partnerships with Famy and Viatris, initiation of clinical trials, receipt of data from clinical trials, submission and receipt of regulatory approvals, business strategy and potential growth, timelines, and scope for global commercialization of Nyxol. These forward-looking statements are based upon Ocuphire’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: (i) the success and timing of regulatory submissions and pre-clinical and clinical trials, including enrollment and data readouts; (ii) regulatory requirements or developments; (iii) changes to clinical trial designs and regulatory pathways; (iv) changes in capital resource requirements; (v) risks related to the inability of Ocuphire to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; (vi) legislative, regulatory, political and economic developments, (vii) changes in market opportunities, (viii) the effects of COVID-19 on clinical programs and business operations, (ix) risks that the partnerships with Famy and Viatris may not facilitate the commercialization or market acceptance of Ocuphire’s product candidates; (x) the success and timing of commercialization of any of Ocuphire’s product candidates and (xi) the maintenance of Ocuphire’s intellectual property rights. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors detailed in documents that have been and may be filed by Ocuphire from time to time with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Ocuphire undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Contacts

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Source: Ocuphire Pharma